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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,418	07/07/2000	Raymond P. Johnston	54971USA3A.006	8574

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/612,418

**Applicant(s)**

JOHNSTON ET AL.

**Examiner**

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13, 39-41, 43-46, 49, 50, 53-61, 72-75, 77 and 81-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 39-41, 43-46, 49, 50, 53-61, 72-75, 77 and 81-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

In view of the appeal brief filed on 2/7/05, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claims 1-9, 13, 39-41, 43-46, 49-50, 53-61, 72-75, 77, and 81-85 are pending. The new matter rejection under 35 USC 112, and the rejection of claims 1-7, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 81, and 83-85 over CHRISTIAN (US 4,673,657) are hereby withdrawn in view of the arguments filed 2/7/05.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 13, 39-41, 43-46, 49-50, 53-61, 72-75, 77, and 81-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly

point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a film layer with microchannels adapted to provide fluid flow from an acquisition zone to a detection zone "by spontaneous fluid transport." In previous office actions, the examiner stated that no specific definition for "spontaneous fluid transfer" was provided by the specification, and interpreted "spontaneous" to mean "occurring without apparent external cause." On page 9 of the response filed 2/7/05, applicant stated that that this interpretation is incorrect and that the "spontaneous" refers to a property of the microchannels. Applicant then provides several apparent definitions of the term with regard to the microchannels. The first is that of "wicking" a fluid sample; i.e. "spontaneously" wicking or transporting a fluid, as set forth on page 10 of the specification. Another appears to be that of "capillary action", as set forth on page 24 of the specification. The third, as set forth on lines 5-6, page 10 of the response, appears to agree with the original interpretation by the examiner: "fluid transport without the aid of any structure "external to the microchannels" through which the fluid is transported." As the phrase "spontaneous fluid transport" is not specifically defined anywhere in the originally filed disclosure, and the response filed 2/7/05 renders it unclear exactly WHAT definition for fluid transport is intended by applicant, the claims are indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-7, 13, 39-41, 43-46, 53, 54, 60-61, 72-75, 81, and 83-85 are rejected under 35 U.S.C. 102(e) as being anticipated by ALAJOKI et al. (US 6,416,642).

Applicant's arguments filed 2/7/05 have been fully considered but they are not persuasive. In response to the argument that the wicking material of ALAJOKI is at least partially external to the channel and is not part of the thin film forming the channel, it is noted that his absorbent material may be placed in a well channel (col. 7, lines 11-14). ALAJOKI specifically states that his wick may be internal to his device and that it may be placed "entirely within" a channel (col. 10, lines 60-64). Further, ALAJOKI teaches that his "wick" may be a polymeric material, and may comprise a variety of polymers (col. 2, line 58-col. 3, line 3) which are the same as materials contemplated for the instant invention (see p. 12 of the instant specification). As applicant argues that at least one interpretation of "spontaneous fluid flow" includes wicking (p. 9 of the response), and the instant specification specifically supports this interpretation at pages 24-26), then ALAJOKI's teaching for a wick meets the limitation for "spontaneous fluid transport" according to this interpretation. Where "spontaneous" is interpreted to mean "without external cause" then it is noted that ALAJOKI's wick does not require any force

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or "cause" external to the device for fluid transport. Applicant attempts to define "spontaneous fluid transport" as occurring without a structure "external to the microchannels" through which the fluid is transported. However, this definition is an interpretation by applicant and is not a particular definition set forth in the specification, thus it is not a limitation of the claims. It is noted that the claims do not limit the fluid transport to occur without a structure "external to the microchannels" and applicant is reminded that limitations from the specification may not be "read into" the claims. Further, where the wick is placed "entirely within" a channel, as taught by ALAJOKI as one embodiment of his invention, above, the wick is NOT external to the channel. For these reasons, applicant's arguments are not persuasive, and the rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-9, 41, 46, 60-61, and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over TSO et al. (US 6,613,560).

TSO teaches a microanalytical device comprising a plurality of reaction zones in fluid communication via microchannels (col. 9, lines 7-30). TSO teaches that his device may be made from a polymeric material (col. 10, lines 18-28) and teaches that the surfaces of the device may be coated with polyvinyl alcohol and other polymers in order to provide desirable surface properties (col. 10, line 58-col. 11, line 6). TSO teaches that his microchannels are continuous between his reservoir/reaction chambers, microchannels and fluid conducting means (col. 13, lines 8-12) and may have a variety of configurations (col. 12, lines 32-58). TSO also teaches that a reservoir means may comprise detection reagents (col. 12, lines 65-67 and col. 14, lines 32-39). TSO teaches a variety of detection methods, thus teaching detection of at least color change, fluorescence, light absorption, and light transmission (col. 18, lines 1-4). TSO teaches that her detection reagents may include a dye or fluorescent indicator (col. 14, lines 35-39). TSO teaches that sample may be introduced into his device by spontaneous fluid displacement (col. 18, lines 54-57), and teaches that fluids may be introduced into his device via an "inlet port", thus making obvious "drawing" of a sample into an acquisition zone (reservoir) through an opening (port) in a microchannel. While TSO teaches that multiple reaction zones/reservoirs may be in fluid communication via microchannels

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(col. 9, lines 7-30), teaches that reaction zones may contain detection reagents (col. 12, lines 65-67), and teaches that a reaction product may be analyzed prior to removal from the device (col. 7, lines 7-8), she does not specifically teach a detection zone facilitating detection of a characteristic of a fluid sample.

It would have been obvious to one of ordinary skill in the art at the time of invention to have included one of the detection reagents taught by TSO in a reaction chamber fluidly connected to but different from a reservoir for sample uptake (i.e. an acquisition zone) in the multiple reservoir/reaction zone device taught by TSO, where the motivation would have been to detect reagents after separation/purification in a microchannel, as taught by TAO (col. 12, lines 33-58).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
8/8/05